

Device Safety

Handling adverse event reports

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WHAT HAPPENS after you report an adverse event involving a medical device to MedWatch, the FDA's Medical Products Reporting System? The FDA's Center for Devices and Radiological Health (CDRH) handles the report and follows up as necessary.

As the process begins, the information is entered in a database and a clinical analyst is assigned to review the report. The pool of analysts consists of 14 nurses with advanced degrees or expertise in specific areas and a nuclear medicine technologist. The analyst evaluates the nature, scope, and magnitude of the reported event and reviews the database for similar events, then determines whether follow-up investigation is warranted.

If an immediate review of manufacturing and complaint records is needed, the CDRH may inspect the facility where the device was manufactured. In many cases, though, the analyst sends a letter to the manufacturer, the facility where the incident occurred, or the person who reported the incident, asking for more specific information. The manufacturer may also be asked about any other adverse events reported for the involved device or similar ones and what corrective action was taken. The analyst then reviews the information to determine whether further FDA action is needed.

Measures may include regulatory action (such as a recall), user notification of a problem, or a press release warning the public of potential hazards associated with the device. Even if no immediate action is warranted, the report of the event remains in the database for future research and monitoring.

If a death, serious injury, or malfunction involving a medical device occurs where you practice, notify the person at your facility who's responsible for reporting such problems or call MedWatch at 1-800-FDA-1088. Visit the CDRH homepage at www.fda.gov/cdrh/safety.html to learn about FDA safety alerts and public health advisories. **N**

Although you need to support the adverse event-reporting policy of your health care facility, you may voluntarily report a medical device that doesn't perform as intended by calling MedWatch at 1-800-FDA-1088 (fax: 1-800-FDA-0178). The opinions and statements in this report are those of the author and may not reflect the views of the Department of Health and Human Services. Device Safety is coordinated by Beverly Gallaresi, RN, BS, MPH.